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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,249

09/28/2004

Shunichi Kuroda

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EXAMINER

PENG, BO

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,249	Applicant(s) KURODA ET AL.	
	Examiner BO PENG	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 4, 10-13, 17-21, 23 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-9, 14-16, 22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/28/04; 12/23/04; 7/25/08 & 9/5/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction election

1. Applicant's election without traverse of Group I (Claims 1-16 and 18-27), and species of (a) a cancer specific antibody, (c) binding to a ZZ tag fused (Claims 3 and 22) and (e) the HBsAg lacks some of amino acids in a pre-S region (Claim 9), in the reply filed on March 4, 2009, is acknowledged. The requirement is still deemed proper and is therefore made FINAL.
2. Accordingly, Claims 1-28 are pending. Claims 4, 10-13, 17-21, 23 and 26-28 are withdrawn from further consideration by the Examiner under 37 C. F. R. 1.142(b) as being directed to a nonelected invention. Claims 1-3, 5-9, 14-16, 22, 24 and 25 are examined in this Office action.

Foreign Priority

3. Applicant's provision of foreign priority documents Japan 2002-97424 and Japan 2003-45088 is acknowledged. It is noted, however, that English translations of the foreign priority documents have not been provided. Applicant is reminded that such priority for the claimed inventions requires support of written description and enablement under 35 U.S.C. 112, first paragraph, in the priority document. Since the English translations of the foreign priority documents have not been provided, it is not clear whether the document provide a written description for the instant claims. Therefore, the priority date is deemed to be March 26, 2003, the filing date of PCT/JP03/03694.

Information Disclosure Statement

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4. Applicant's IDSs, filed on September 28, 2004, December 23, 2004, July 25, 2008, and September 5, 2008, are acknowledged and considered, except for some foreign references without English translations that have been crossed out. The full context of the cited foreign references couldn't be determined from only the English translations of Abstracts.

Specification

5. The amendment filed December 16, 2008, is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New sequence listing and CRF, submitted on December 16, 2008, contains additional sequences of SEQ ID NOs: 30 to 244 that were not disclosed in the sequence listing and CRF filed September 28, 2004, and not supported by the original disclosure. Applicant is required to cancel the new matter in both sequence listing and CRF the reply to this Office Action.

Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

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8. Claim 2 is indefinite because the limitation “cancer specific antibody” is not explicitly defined in either the claims or the specification. The term “cancer specific antibody” is not defined by the art, either. One of ordinary skill in the art cannot be reasonably apprised of the metes and bounds of the invention without a clear definition of “cancer specific antibody”.

9. Claims 8 and 9 are indefinite. HBV surface antigen comprises multiple proteins, called L, M or S surface proteins. Conventionally, HBV surface antigen (HBsAg) refers S (small) surface antigen, which does not comprise pre-S1 or pre-S2 peptide, in the scientific literature. However, inconsistent with the scientific literature, the specification appears to use both terms “HBV surface antigen L protein” and “HBsAg” to refer the HBV surface antigen L protein. Claims 8 and 9 appear to refer to the HBV surface antigen having a pre-S region. Because of inconsistency of the term “HBV surface antigen” between the claims and the scientific literatures, one of ordinary skill in the art cannot be reasonably apprised of the metes and bounds of the invention. Appropriate correction is required. **Note:** For the purpose of the examination, Claim 8 read on “wherein the particle-forming protein comprises a modified hepatitis B virus surface antigen large (L) protein”.

Claim Rejections - 35 USC § 112, first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-3, 5-9, 14-16, 22, 24 and 25 are rejected under 35 U.S.C. 112, first

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paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

“[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’” *Genentech Inc. v. Novo Nordisk* 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997); *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); See also *Amgen Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir. 1991); *In re Fisher* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Further, in *In re Wands* 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court stated:

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* [230 USPQ 546, 547 (BdPatAppInt 1986)]. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

12. Claims 1-3, 5-9, 14-16, 22, 24 and 25 are directed to a drug that comprises hollow

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nanoparticles of a particle-forming protein, the hollow nanoparticles displaying an antibody against a specific cell or specific tissue, and encapsulating a substance to be transferred into a cell for treating a disease (Claims ...), wherein the particle-forming protein comprises HBsAg L protein (Claims 8 and 9), wherein the disease-treating substance is a thymidine kinase gene of herpes simplex virus type 1 (HSV1 tk), wherein the drug is administered to the human body through intravenous injection. It is noted that a “drug” means a medicine for treating a disease, which requires providing a clinical benefit. Since there are no structural limitations to “a substrate” and no indication what specific diseases/cancer (Claim 1/2) the claimed drug can treat, the scope of the claims encompasses “a drug” comprising any nanoparticles that contain any substances for treating any disease in any animal including humans. In supporting the claims, the specification teaches making a HBsAg particle comprising a peptide SEQ ID NO: 29 (ZZ tag) and an antibody 7G7B6 (mouse mAb to human EGF receptor, EGFR), called as HBsAg-ZZ Tag-Ab, which further encapsulates a HSV tk gene; (Example D4 and D6). The specification teaches that such particles can reduce the size of a tumor in nude mice.

13. To put the uncertainties of drug development in perspective, the art teaches it is highly unpredictable if any chemicals, such as the claimed nanoparticles, can be “a drug” for treating diseases, providing clinical benefit. The state of the art indicates “The process of drug discovery and development is a long, complex and multi-stage process where odds of success, in retrospect, are low. For drug, in general, only 20% of drug discovery projects leads to a clinical candidate and only 10% of compounds that enter clinical development achieve registration” (Pauwels, 2006). More importantly, Pauwels points out: “Analysis of the reasons for apparently low and even declining success rate reveals

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that projects mainly fail because drug candidates prove inactive in animal models or in patients, display unacceptable toxicity or cause undesirable side-effects upon *in vivo* administration” (Pauwels, 2006). Thus, the state of the art has shown that drug development is unpredictable; neither is the claimed drug comprising any nanoparticles that contain any substances. *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Although the specification disclosed that the complex of HBsAg comprising HSV1-*tk* gene reduced the size of tumors in nude rats, the art has not indicated that nude rats are an art-recognized model for human diseases. The specification has not provided *in vivo* or *in vitro* data showing that the claimed drugs of any nanoparticles displaying a so called “cancer specific antibody” and containing any substances can be effective in treating any diseases, providing clinical benefit. The specification fails to show the correlation between the diseases and the capability of treatment by claimed drugs of nanoparticles comprising an undefined substance. In the absence of evidence, one of skill in the art is unable to fully predict the possible clinical application and benefit of the claimed drugs; therefore, would not know how to use the alleged drugs.

14. Moreover, the claims also require making nanoparticles, which display an antibody to a cell or a tissue, and also encapsulate a substance therein. However, the state of prior art also teaches that it is unpredictable how to assemble a foreign substance into a viral particle because formation of a viral particle requires specific packaging/assembly signals and has structural restrictions on inserted sequences and insertion sizes. The structure of foreign substances can affect the formation of nanoparticles. For example,

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Ward *et al* (Virus Genes, Vol. 23: p. 97-104, 2001) tried to package the hepatitis C virus (HCV) core protein into HBsAg particles. Ward *et al* found that only limited chimeric proteins were packaged into viral particles, due to poor expression and the size limit to the insert (see in particular the abstract and Fig. 3). Therefore, the outcome of trying to assemble uncharacterized substances into any particle-forming proteins, obtaining stable nanoparticles is unpredictable in the art. The specification, however, has not shown how to assemble uncharacterized substances into any other particle-forming proteins. The specification has provided little guidance as to what are the structural requirements for encapsulating a substance into any nanoparticle. Thus, one of ordinary skill in the art would not know how to make a nanoparticle comprising any substance.

15. Since the scope of the claims clearly covers drugs comprising undefined nanoparticles for treating un-specified diseases in humans, and in order for the full breadth of the invention to be enabled, a skilled artisan would have to make and test all particle-forming proteins to see if they can encapsulate any substance, and test them to see if they can be “a drug” for treating undefined diseases, such as all unspecified cancers. Such drug screening would entail an undue amount of experimentation. In view of the empirical and unpredictable nature of drug development and lack of guidance and working examples in the specification, one skilled in the art would not know how to use the claimed drugs, and would not know how to make the claimed nanoparticles that can encapsulate any substance of the instant invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 1, 5-7, 14, 16, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by O’Riordan (WO 99/40214, International publication date: August 12, 1999).

18. Claims 1, 5-7, 14, 16, 24 and 25 are directed to a drug that comprises hollow nanoparticles of a particle-forming protein, the hollow nanoparticles displaying an antibody against a specific cell or specific tissue, and encapsulating a substance to be transferred into a cell for treating a disease, wherein the disease-treating substance comprises a gene, wherein the antibody is a single chain antibody fused with the particle-forming protein.

19. O’Riordan teaches a nanoparticle drug delivery system for delivering a nucleic acid drug, wherein the nucleic acid drug delivery system comprises a replication-deficient adenoviral particle (Ad) containing *CFTR* gene (a nucleic acid drug), wherein in the Ad/*CFTR* particle is complexed with an antibody targeting molecule, such as Fab (See e. g. Abstract and Figure, p. 36-38, p. 47-50. and Examples). Since O’Riordan’s nucleic acid drug delivery system has all the structural features of the claimed hollow nanoparticles of Claims 1, 2, 5-7, 14, 16, 24 and 25, the instant claims are anticipated by O’Riordan.

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20. Claims 1, 5-9, 14, 16, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuroda (WO 01/64930, which is PCT/JP01/00926, International publication date: September 7, 2001, cited in IDS. The US2003/0092069, which is the National stage of PCT/JP01/00926, is cited as the English translation of WO 01/64930).

21. Kuroda (WO 01/64930) teaches hollow nanoparticles composed of HBsAg L protein a biorecognition molecule to introduce a substance (gene, protein, compound, etc.) into the target cells or tissue, wherein the biorecognition molecule on the hollow nanoparticles is an antibody; see the English translation of Abstract (WO 01/64930), and see also see Para [0009]-[0016] and the claims of US2003/0092069. Kuroda (WO 01/64930) teaches that the gene encoding HBsAg L protein was mutated in the region of the human liver cell-recognition site (the 3rd to 77th amino acids of the preS region), by introduction of restriction site NotI in the gene); see [0069]-[0072] and Example C of US2003/0092069. This teaching indicates that the HBsAg L protein particle “is modified to lack some of amino acids in a pre-S region” (Claim 9). Since Kuroda (WO 01/64930) teaches a nanoparticle that meets the limitations of Claims 1, 5-9, 14, 16, 24 and 25, The instant claims are anticipated by Kuroda (WO 01/64930).

22. Claims 1-3, 5-7, 22, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Ojala K, *et al.* (Biochem Biophys Res Commun. 2001;284(3):777-84).

23. Ojala teaches baculovirus (nanoparticle) displaying either a functional single chain antibody fragment (scFv) specific for the carcinoembryonic antigen (CEA) or the synthetic IgG binding domains (ZZ) derived from protein A of *Staphylococcus aureus*,

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see e.g. Abstract. The anti-CEA scFv displaying baculovirus was shown to bind specifically to CEA expressing cells (PC-3). Similarly, the virus displaying the ZZ domains of protein A was targeted to BHK cells via binding of an appropriate IgG antibody. In addition, the baculovirus vectors were engineered to incorporate a reporter gene encoding the enhanced green fluorescent protein (EGFP). In all cases, the reporter gene was expressed in the transduced mammalian cells as shown by fluorescence microscopy and flow cytometric analyses. Ojala teaches that such viral particles displaying specific ligand binding moieties have raised an increasing interest in the area of targeted gene therapy, see e.g. Abstract. Since Ojala's baculovirus (nanoparticle) displaying either an antibody or ZZ-Tag, and encapsulating EGFP gene meets the every structural limitations of Claims 1-3, 5-7, 22, 24 and 25, the claims are anticipated by Ojala.

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of their obligation under

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37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

25. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over O’Riordan (WO 99/40214, as applied to Claims 1, 2, 5-7, 14, 16, 24 and 25 above, and further in view of Rosenfeld (1997; Annals of Surgery 1997; 225(5):609-618).

26. Claim 15 is directed to the nanoparticle of Claim 14, wherein the gene comprises HSV-1 *tk* gene.

27. The relevance of O’Riordan is set forth *supra*. However, O’Riordan does not explicitly teach that an Ad particle containing HSV-1 *tk* gene.

28. Rosenfeld teaches an adenoviral particle comprising HSV1 tk gene (AdCMVHSV-1tk) (pp. 610 and 611). Rosenfeld shows that Ad/HSV-1tk particles are highly transducible to human pancreatic carcinoma cells and the resulting carcinoma cells expressing HSV-1 tk protein is more sensitive to chemotherapy agent ganciclovir (GCV) (p. 611). Rosenfeld teaches that *in vivo* administration of AdCMVHSV-1tk and GCV results in reduced tumor burden (p. 614 and 615). Rosenfeld suggests a strategy for human pancreatic carcinoma using HSV-tk and GCV in molecular chemotherapy (Abstract).

29. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the nanoparticle of O’Riordan to express HSV-1 *tk* as taught by Rosenfeld. The skilled artisan would have been motivated to do so, and would have a reasonable expectation of success, given the knowledge that a nanoparticle

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comprising Ab can be used as a drug delivery system for delivering a nucleic acid drug, as taught by O’Riordan and also given the knowledge that the HSV-1 tk substance transferred into a cell can be used for treatment of a cancer, as taught by Rosenfeld. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 1-3, 5-7, 22, 24 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-11 of 10/594, 612 (‘612). Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined application claim would have been obvious over Claims 1-11 of 10/594, 612 (‘612), In view of Ojala K, *et al.* (Biochem

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Biophys Res Commun. 2001 Jun 15;284(3):777-84).

32. Claims 1-11 of 10/594, 612 ('612) are directed to a sensor tool of nanoparticles comprising biorecognition molecules.

33. The relevance of Ojala K, *et al.* is set forth *supra*. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the nanoparticles having biorecognition molecules for targeted gene therapy as taught by Olala.

34. This is a provisional obviousness-type double patenting rejection.

35. Claims 1-3, 5-9, 14-16, 22, 24 and 25 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-3, 6, 8 and 9 of co-pending application 11/987,476. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same products. This is a provisional obviousness-type double patenting rejection.

Remarks

36. No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on Tu-F, 8:30-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/BO PENG/

Primary Examiner, Art Unit 1648